



Wednesday, September 15, 2021

Sent via Email

To: 'Peter_Fise@finance.senate.gov' <Peter_Fise@finance.senate.gov>
Cc: 'Anna_Kaltenboeck@finance.senate.gov' <Anna_Kaltenboeck@finance.senate.gov>;
'Raghav_Aggarwal@finance.senate.gov' <Raghav_Aggarwal@finance.senate.gov>;
'James_Maloy@finance.senate.gov' <James_Maloy@finance.senate.gov>

Subject: Support of legislation for Congress to amend the CAA through reconciliation to ASP+15% for skin substitute products

Dear Peter,

I serve as the executive director of the Alliance of Wound Care Stakeholders, a nonprofit multidisciplinary trade association of physician specialty societies, clinical and patient associations whose mission is to promote evidence-based quality care and access to products and services for people with chronic wounds (diabetic foot ulcers, venous stasis ulcers, pressure ulcers and arterial ulcers) through effective advocacy and educational outreach in the regulatory, legislative, and public arenas. Our clinical specialty societies and organizations possess expert knowledge in treating complex chronic wounds/ulcers and in wound care research. The Alliance is viewed as the umbrella association for all of wound care since our membership includes not only the clinical and patient associations mentioned but also wound care clinics and business entities (manufacturers and distributors). A list of our members can be found on our website:

<http://www.woundcarestakeholders.org/about/members>

We are in general support of legislation for Congress to amend the CAA through reconciliation to ASP+15% for skin substitute products before the new requirements under Part B go into effect next year. We would appreciate seeing the language however before providing our full support. This is an important issue for our members. Please recognize that this small change would allow skin substitute products to remain in private physician offices while retaining the new reporting requirements instituted in the omnibus. The effect will have a dramatic impact on minority and underserved communities, which disproportionately suffer from skin ulcers and other skin-related complications that require skin substitute products. Without this change, it is likely that these populations will see access to early treatment dwindle, leading to more amputations, more hospitalizations and poorer health outcomes.

Here is background information for your consideration:

- The 2020 Omnibus included language requiring all drug manufacturers covered under Medicare Part B to report average sales price (ASP) information to the Secretary of HHS beginning on January 1, 2022. (Attached) This provision added a new requirement under Part B for manufacturers that do not have a rebate agreement through the Medicaid Drug Rebate Program to report ASP information, including skin

5225 Pooks Hill Rd | Suite 627S | Bethesda, MD 20814

T 301.530.7846 | C 301.802.1410 | F 301.530.7946

marcia@woundcarestakeholders.org

substitute products. While reporting ASP versus WAC/AWP can potentially save Medicare money on the reimbursement of the individual product, it would create unintended consequences of significantly higher overall costs for the health system accompanied by a significant decrease in the quality of the patient access and outcomes.

- Doctors in private practice that choose to retain the patient despite lower reimbursement would no longer offer be able to offer certain advanced skin substitutes with each treatment, impacting patient outcomes significantly. Instead, patient conditions would be more likely to progress to infection, amputation and hospitalization from the more traditional wound care modalities that have already been proven ineffective for these patients. This is not a sustainable model for small physician practices such as podiatrists, especially practices that serve minority and underserved populations.
- Physicians in a private setting receiving a lower reimbursement for advanced treatments because of the reporting changes made in the 2020 CAA would, in most cases, limit patient access to advanced treatment.
- Loss of patient access to advanced treatments in this important site of care would lead to infection, amputation, and hospitalization – which result in poorer health outcomes for patients. Either hospital setting comes with a significantly higher overall cost to the payer as studies show long-term costs of amputations are between \$100k-\$500k.

Please contact me if I can answer any questions for you on this important issue. Thank you so much.

Sincerely,

Marcia Nusgart, R.Ph.

Executive Director

Alliance of Wound Care Stakeholders

5225 Pooks Hill Road, Suite 627S

Bethesda, MD 20814

tel 301.530.7846 | cell. 301.802.1410

www.woundcarestakeholders.org